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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte SUBRAMANIAN S. VENKATRAMAN, THOMAS M. STEIN,
JAMES SNIDER, and RICHARD D. HAMLIN

Appeal 2008-2250
Application 10/611,531
Technology Center 1600

Decided: December 22, 2008

Before TONI R. SCHEINER, DEMETRA J. MILLS, and ERIC GRIMES,
Administrative Patent Judges.

MILLS, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF CASE

The following claim is representative.

12. A transdermal drug delivery device comprising:
- (a) a backing layer;
 - (b) a drug reservoir on or adjacent the skin-proximal side of the backing layer, said drug reservoir comprising a melt-blended mixture of at least one drug and a polymer consisting of polyurethane polymer, said polyurethane polymer having a process temperature of less than about 150 °C, wherein the polymer can be directly melt blended with the at least one drug at less than about 150 °C without an organic solvent to result in the drug reservoir; and
 - (c) means for maintaining the device in drug transmitting relationship with a body surface or membrane.

Cited References

Szycher et al.	US 4,638,043	Jan. 20, 1987
Alexander et al.	US 5,066,648	Nov. 19, 1991
Jaeger et al.	US 5,273,757	Dec. 28, 1993
Castellana	US 5,599,289	Feb. 4, 1997
Chono et al.	US 6,139,866	Oct. 31, 2000

Grounds of Rejection

1. Claims 12, 13, 15-20, 22, 33, and 54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Szycher.
2. Claims 12-20, 22, 33, 54, and 59-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher.
3. Claims 12-33, 54-57, and 59-60 rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher in view of Jaeger or *vice versa*.
4. Claims 21, 28, 29, and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher in view of Jaeger and further in view of Chono.

5. Claims 21, 28 and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher in view of Jaeger, and further in view of Alexander.
6. Claim 32 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher in view of Jaeger, and further in view of Castellana.

1. Claims 12, 13, 15-20, 22, 33, and 54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Szycher.

ISSUE

The Examiner argues that the burden of proof was properly shifted to Appellants under the principles of *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). (Ans. 17.)

Appellants contend that the uncured oligomer of Szycher would not be considered a melt-blendable polyurethane. (App. Br. 13.)

Thus, the issue is whether the Examiner properly shifted the burden of proof to Appellants to show that the melt-blendability property claimed is not a property of the polyurethane of Szycher.

FINDINGS OF FACT

1. According to the Examiner, Szycher “discloses a transdermal drug releasing patch that is non-toxic, noncarcinogenic and biocompatible, oxygen and water vapor permeable, flexible, and can incorporate a wide variety of drugs for a controlled, sustained release to the wearer (abstract; col. 2, ll. 56-57).” (Ans. 4.)

2. Szycher discloses “[t]he patch comprises support layer, i.e. backing layer (12); a polymer layer of polyurethane containing a drug (16) and a pressure sensitive adhesive layer to fix the patch to the skin (18), i.e. maintaining the patch in drug transmitting relationship with the body surface (col. 2, lines 13-22; col. 4, lines 45-57; figures 2 and 3).” (*Id.*)
3. Szycher discloses the drug containing layer is made of polyurethane and comprises the reaction product of (1) diisocyanate, (2) a glycol having a molecular weight in the range of 500-5000 and (3) an acrylyl chain terminator (Szycher, col. 3; ll. 40-50; Claim 1). The polyurethane may also include propylene glycol or polyethylene glycol. (Col. 4, ll. 1-9.)
4. The Examiner finds that Szycher discloses “[t]he polyurethane polymer is liquid at room temperature to facilitate admixture of drug to form a homogenous blend, and this implies that the melt temperature of the polyurethane is below 100° C and the drug can be blended into the polymer at this temperature (col. 2, lines 42-46).” (Ans. 4.)
5. Szycher discloses “[t]he polyurethane polymer does not contain any solvents (col. 3, lines 32-33).” (*Id.*)
6. According to the Specification, “[t]he polyurethanes suitable for practice of this invention are the reaction product of aliphatic organic diisocyanates, high molecular weight polyether polyols, and low molecular weight glycols” (Spec. 14: 14-16).
7. According to the Specification, page 16, lines 3-13, preferred polyurethanes of the invention comprise a diisocyanate, a polyether alcohol having a molecular weight of 1000-2000 Da and a diol chain extender. The claimed polyurethane may also incorporate a propylene glycol. (Spec. 15, ll. 17-20).

8. The claims recite a “polyurethane polymer” and do not specify that the polyurethane polymer be cured or uncured. Thus we interpret the term “polyurethane polymer” with its broadest reasonable interpretation as encompassing both cured and uncured forms of the polymer.

PRINCIPLES OF LAW

In order for a prior art reference to anticipate a claimed invention, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.” *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). “The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *Id.* (citations omitted). *See also Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 843-47 (Fed. Cir. 1992).

In addition, our mandate is to give claims their broadest reasonable interpretation.

Giving claims their broadest reasonable construction “serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified.” *Yamamoto*, 740 F.2d at 1571; *accord Hyatt*, 211 F.3d at 1372; *In re Zletz*, 893 F.2d 319, 322 (Fed.Cir.1989) (“An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.”).

In re American Academy Of Science Tech Center, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

In re Best, 562 F.2d 1252, 1255 (CCPA 1977) is directed to a particular set of circumstances where Examiners in the USPTO cannot readily determine whether a difference exists between the subject matter of a given claim and a particular prior art document. Typically these circumstances arise in the context of a claim directed to a compound or composition where the claim describes a property or a function of the compound or composition which the prior art reference does not address. These circumstances can also arise where as here the claim is directed to a transdermal drug delivery device. As explained in *Best*, if the claimed and prior art products are identical or substantially identical, the USPTO can require an applicant to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product. In order to invoke the principles of *In re Best*, the Examiner must first make factual findings which support the conclusion that the claimed and prior art products *prima facie* are "identical or substantially identical." That determination must be made case-by-case based upon the facts in the individual case.

In *In re Best*, 562 F.2d at 1255 the court stated:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to

manufacture products or to obtain and compare prior art products.

ANALYSIS

Appellants contend that

Melt-blendability is a property of the polyurethane in the claimed device. In the presently claimed invention, the polyurethane polymer can be directly ***melt blended*** with the at least one drug at less than about 150°C without an organic solvent. The polyurethane in the [claimed] device must be able to be processed by melt-blending. There is no indication that the material described by Szycher can be processed in melt-blending.

(App. Br. 15.) Appellants argue there is no indication that the polyurethane of Szycher can be processed at a temperature of less than about 150°C without an organic solvent. (App. Br. 15.)

The Examiner finds that the polyurethane polymer of Szycher is a “liquid at room temperature to facilitate admixture of drug to form a homogeneous blend, and this implies that the melt temperature of the polyurethane is below 100°C and [that] the drug can be blended into the polymer at this temperature.” (Ans. 4.) The Examiner further argues that the “patentability of a product does not depend on its method of production.” (Ans. 16.)

We acknowledge, as did the Examiner, that Szycher describes processing a polyurethane at a temperature of less than about 150°C (FF4) without an organic solvent (FF5). We also acknowledge that the melt-blendability claim limitation is product by process language, and that the issue is not whether Szycher describes a process of melt blending, but

whether one of ordinary skill in the art would consider the final polyurethane products to be the same. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). “Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.” *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983).

So ultimately, this case turns on whether the Examiner properly shifted the burden to Appellants to show that the claimed product and the product of Szycher are the same.

While the Examiner found many features of the polyurethane of Szycher were the same or substantially the same as those of the claimed polyurethane transdermal drug delivery device, such as having a drug incorporated in polyurethane, the processing of polyurethane at a temperature of less than about 150°C (FF4) and the absence of an organic solvent (FF5), we think a greater showing is required to shift the burden to Appellants to show that the claimed product and the product of Szycher are not the same.

For example, while both polyurethanes incorporate diisocyanates, chain extenders and may include propylene glycol, the examiner has not shown that the glycol having a molecular weight in the range of 500-5000 of the polyurethane of Szycher is the same or substantially the same as the high molecular weight polyether polyols disclosed in the Specification as one of

the components of “[t]he polyurethanes suitable for practice of this invention” (FF6). In order to properly shift the burden of proof to Appellants such evidence is required by the Examiner.

CONCLUSION OF LAW AND DECISION

The Examiner has not properly shifted the burden of proof to Appellants to show that the claimed product and the product of Szycher are different. In view of the above, the anticipation rejection over Szycher is reversed.

2. Claims 12-20, 22, 33, 54, and 59-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher. 3. Claims 12-33, 54-57, and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher in view of Jaeger or *vice versa*. 4. Claims 21, 28, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher in view of Jaeger and further in view of Chono. 5. Claims 21, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher in view of Jaeger, and further in view of Alexander. 6. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher in view of Jaeger, and further in view of Castellana.

Each of these rejections relies on Szycher, discussed above, and has the same deficiencies as the anticipation rejection over Szycher. The Examiner has not met his burdent of showing that the secondary references relied upon that overcomes this deficiency in Szycher. Rejections 2-6 are reversed.

Appeal 2008-2250
Application 10/611,531

CONCLUSION OF LAW

The anticipation and obviousness rejections are reversed.

REVERSED

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